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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,877	09/22/2003	David Boyd Melvin	MELV / 27US	1155
26875	7590	01/27/2006	EXAMINER	
WOOD, HERRON & EVANS, LLP 2700 CAREW TOWER 441 VINE STREET CINCINNATI, OH 45202			CHATTOPADHYAY, URMI	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/667,877	MELVIN, DAVID BOYD
	Examiner Urmi Chattopadhyay	Art Unit 3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 September 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-6,8-11,13-17,19-21,23 and 24 is/are rejected.
- 7) Claim(s) 7,12,18 and 22 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 22 September 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/15/04; 9/7/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: “clip structure 38” mentioned on page 18, lines 14-15 is not shown in the drawings. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities: on page 17, line 10, “come” should be changed to --dome--. Appropriate correction is required.

Claim Objections

3. Claims 4 and 9 are objected to because of the following informalities:

- Claim 4, a period is missing at the end of the claim.

b) Claim 9, line 3, it appears that --to-- or --with-- should be inserted after “coupled”.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 4, 6 and 8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. With respect to claims 4 and 6, the locking/suture structure is claimed to be positioned internally of at least one of the atria or great vessels. This defines the locking/suture structure with respect to a part of the body, which is not statutory subject matter. The examiner suggests inserting --configured to be-- before “positioned” on line 2 of each of claims 4 and 6. Claim 6 further claims the atria or great vessels as part of the claimed invention by limiting the sutures as “spanning a wall of one of the atria and great vessels”. Since a part of the body is not statutory subject matter, the examiner suggests changing “spanning” to --adapted to span-- and “anchoring” to --anchor--. Along these same lines, --configured to be-- should be inserted after “cushion” on line 1 of claim 8.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 9-11, 13-17 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Benetti et al. (USPN 5,727,569, as cited in applicant's IDS).

Benetti et al. discloses a heart-mounted structure with all the elements of claim 9. See Figure 2 for a dome structure (1) having openings (2 and 9) and a bottom surface (6) shaped to conform to the surface of the heart (column 3, lines 9-11). Because the bottom surface has at least one opening (2) that stably affixes the dome structure (1) to the heart surface using negative pressure, the dome structure is configured so that it is capable of being coupled to a basal surface of a ventricular portion of the heart, and proximate the opening (2), is configured so that it is capable of interfacing with an atrial chamber of the heart.

Claims 10 and 11, see column 5, lines 4-7 for dome structure material.

Claim 13, see Figure 2 for a plurality of openings (2 and 9) in the dome structure.

Claims 14 and 15, see column 5, lines 24-27 for the dome structure (1) holding, via opening (9), an extension or sleeve (11) capable of interfacing with the atria.

Claim 16, see column 5, lines 4-7 for the materials listed by nature having some texture, thereby providing a textured surface for interfacing with a heart surface.

Claims 17, 19 and 20, see columns 4-5, lines 60-7 for a cushion (7) being between the dome structure (1) and the heart, interfacing with an opening in the dome, and being integral with the dome.

Claim 21, see column 5, lines 31-35 for a ring structure (23) positioned around the opening (9) in the dome structure (1).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-3, 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Melvin (USPN 5,957,977, as cited in applicant's IDS) in view of Benetti et al.

Melvin discloses an actuating element for assisting the operation of a natural heart with all the elements of claim 1, but is silent to the actuating element being anchored to a dome structure as an actuation system. See Figures 5A and 5B and column 3, lines 29-31 for an actuating element (74) being attached to a yoke (70). Benetti et al. teaches a dome structure (1) having a plurality of openings (2 and 9) (claim 5) and a bottom surface (6) shaped to conform to the surface of the heart (column 3, lines 9-11). Because the bottom surface has at least one opening (2) that stably affixes the dome structure (1) to the heart surface using negative pressure, the dome structure is configured so that it is capable of being coupled with a ventricular portion of the heart, and proximate the opening (2), is configured so that it is capable of interfacing with an atrial chamber of the heart. See column 5, lines 4-7 for dome structure materials (claims 2 and 3). The dome structure is used to fix a portion of the surface of a beating heart so that a surgical procedure can more easily be performed. See abstract. It would have been obvious to one of ordinary skill in the art at time of applicant's invention to look to the teachings of Benetti et al. to modify the actuating element of Melvin by anchoring it to a dome structure as an actuation system in order to be able to fix a portion of the surface of the heart so that a surgical

procedure can more easily be performed while actuating the rest of the heart to ensure proper beating. Benetti et al. also teaches a cushion (7) between the dome structure (1) and the heart in order to facilitate forming a tight seal when the negative pressure is imposed to fix the portion of the heart surface, as required by claim 8.

10. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benetti et al. in view of Melvin.

Benetti et al. discloses a heart-mounted structure with all the elements of claim 9, but is silent to the structure further comprising an actuating element, the dome structure configured for interfacing with the element to anchor the element, as required by claim 23. Melvin teaches an actuating element (74) being attached to a yoke (70); see Figures 5A and 5B and column 3, lines 29-31 in order to actuate the heart at a proper rate. See column 2, lines 55-57. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Melvin to modify the heart-mounted structure of Benetti et al. by integrally forming (claim 24) the dome structure to a yoke with actuating element attached thereto. Combining the dome and actuating element will enable fixing a portion of the surface of the beating heart to facilitate surgery while ensuring proper beating of the rest of the heart through actuation.

Allowable Subject Matter

11. Claims 4 and 6 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 101, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

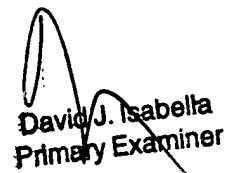
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12. Claims 7, 12, 18 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmī Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David J. Isabella
Primary Examiner

Urmī Chattopadhyay

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